FONSI

FINDING OF NO SIGNIFICANT IMPACT
FOR

Food Additive Petition 7A4556, submitted by Cultor Food Service, Inc., to amend the food additive regulations to permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemical Codex, 4th ed., 1996.

The Scientific Support Branch, Center for Food Safety and Applied Nutrition, has determined that the approval of this petition will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment (EA) prepared using the format described in previous 21 *CFR* 25.31a(a), and on the EA for FAP 5A4478, dated June 24, 1996, which the petitioner incorporated into the current petition by reference. This action will not 1) change the current uses of polydextrose; 2) increase the total yearly market volume of polydextrose used in the United States; and 3) change the level of its use.

Prepared by: ______________________ Date: November 5, 1997
LCDR Sarath Seneviratne, Environmental Officer
Chemistry and Environmental Review Team
Scientific Support Branch

and: ______________________ Date: November 5, 1997
Jeanette G. Glew, Environmental Scientist
Chemistry and Environmental Review Team
Scientific Support Branch

Approved by: ______________________ Date: November 5, 1997
Layla I. Batarseh, Ph.D., Acting Team Leader
Chemistry and Environmental Review Team
Scientific Support Branch

97F-0388

FONSI-1

REVISED MASTER ENVIRONMENTAL ASSESSMENT - POLYDEXTROSE

1. DATE: June 24, 1996

2. NAME OF APPLICANT/PETITIONER: Cultor Food Science, Inc.

3. ADDRESS: 205 East 42nd Street, New York, NY 10017

4. DESCRIPTION OF PROPOSED ACTION:

Requested Approval. The proposed action involves polydextrose, a food additive under 21 CFR 172.841, for which Pfizer Central Research has submitted a Food Additive Petition (FAP 5A 4478) for its use as a bulking agent and texturizer in fruit and water ices. Cultor Food Science, Inc. has acquired all rights and assets regarding said polydextrose, including the rights to pursue this submission, by virtue of the January 29, 1996 acquisition of the former Pfizer Food Science Group. All previously requested uses and their petition numbers are as follows:

	FAP No.
Baked Goods and Baking Mixes (restricted to fruit- custard-, and pudding-filled pies, cakes; cookies; and similar baked products)	9A3441
Chewing Gum	9A3441
Confections and Frostings	9A3441
Dressings for Salads	9A3441
Frozen Dairy Desserts and Mixes	9A3441
Fruit and Water Ices	5A4478
Fruit Spreads	8A4068
Gelatins, Puddings and Fillings	9A3441
Hard and Soft Candy	9A3441
Peanut Spread	7A3998
Sweet Sauces, Toppings and Syrups	9A4126
Tablespreads	2A4332

Need for the Action. Polydextrose is now used by the food industry as a bulking agent, formulation aid, humectant and texturizer in a variety of foods sold throughout the United States and abroad. It is not intended for use in food packaging materials. At this time polydextrose is approved in all the above categories except for tablespreads and fruit and water ices.

Production and Processing Locations and Environments.

Polydextrose is produced - and will be produced for the proposed action - in a facility owned and operated by Cultor Food Science, Inc. ("Cultor Food Science"), PO Box 8266, Terre Haute, Indiana 47808-8266.

The Plant is located in Vigo County, Indiana, eight miles south of Terre Haute and approximately five miles east of the major aquatic feature of the county, the Wabash River. The plant site includes a total of 101 acres consisting of prime farmland interlaced with forested, upland plains terrain. Several residential subdivisions and single family homesteads are located in the vicinity of the plant proper. Pfizer Inc (Pharmaceutical) operates a manufacturing facility immediately adjacent to the Polydextrose manufacturing plant and provides services under contract to the Cultor Food Science operating unit including utilities and waste treatment.

The average elevation of the site is 550 feet AMSL. All production facility surface water drainage is to the north. This drainage includes precipitation run off and noncontact cooling water discharges (from Cultor & Pfizer sources) to Jordan Creek averaging approximately 4 MGD. Jordan Creek also is the receiving stream for effluent from the Pfizer Wastewater Treatment Plant (WWTP) and agricultural/grazing area runoff from Pfizer, and other third party properties. Total stream flow is estimated to be 6-10 MGD. All plant areas are above the 100 and 500 year flood plains.

The water quality of Jordan Creek is good and the creek supports a stream dependent community of aquatic and terrestrial wildlife which are native to this area of Indiana. The stream enters Honey Creek approximately five (5) miles north of the Vigo Plant, which ultimately drains in the Wabash River at an elevation of approximately 440 feet AMSL.

Use and Disposal Locations and Environments.

Polydextrose is used - and will be used for the subject action - in the food industry for production of food products that will be distributed and eaten throughout the U.S. and abroad. Food processors are found in many locations throughout the U.S. and abroad and include many major corporations and independents.

Owing to the nature of polydextrose and its intended uses in foods, there will be no disposal of the product (see Environmental Assessment Technical Assistant Document 2.00, March 1987, p. 7, for definition of disposal).

5. IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE SUBJECT OF THE PROPOSED ACTION:

Name: polydextrose (a randomly bonded condensation polymer of D-glucose with some bound sorbitol and citric acid)

Chemical Abstracts Registry No.: 68424-04-4

Molecular Weight: average - 1500; range 162 - approx. 20,000

Molecular Formula (general): $(C_6H_{10}O_5)n$ (excludes as trivial minor amounts of sorbitol and citric acid)

Physical Description: water-soluble white to light tan colored solid or clear, straw-colored liquid

Additives: may be partially neutralized (with potassium hydroxide) and decolorized; may be mixed with other food substances such as potassium bicarbonate to adjust pH

Impurities: meets Food Chemicals Codex specifications; may contain small amounts of unreacted starting materials (glucose, sorbitol, citric acid), 1, 6-anhydro-D-glucose (levoglucosan), and 5-hydroxymethylfurfural

Structural Formula: Illustration of chemical bonds present in polydextrose are shown in Appendix 1. Polydextrose has been determined to be comprised predominately of glucose moieties in the pyranose form with about 9% in the furanose form. Linkages have been determined to be 1, 6-(~60%), 1,4-(~20%), 1,3-(~20%), with very small amounts of 1,2- and 1,1-linkages. Configurations at the 1-position are estimated to be α: β=1:1. Refer to FAP 9A3441, Section A, for additional information.

6. INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT:

A. Production. Manufacture of polydextrose is presently carried out at the Cultor Food Science plant in Terre Haute, IN.

Manufacture of additional quantities subject to the present action will also be carried out at the Terre Haute facility.

The total poundage of polydextrose produced at this time for all approved uses is given in Confidential Appendix 2. Also included in Appendix 2 is estimated poundage to be produced for pending uses in tablespreads and fruit and water ices The increased production of polydextrose for these pending uses would not be expected to have a significant impact on controls or emissions at the Terre Haute production facility.

While the materials and product in the polydextrose production area are not subject to specific Federal, State and local permitting requirements, release of raw material and finished product to the environment is controlled as delineated below.

1. Manufacturing Emissions - The polydextrose manufacturing process is a condensation polymerization, with all ingoing monomers becoming an integral part of the final product. Extensive experience with the process shows that there are no significant discharges or manufacturing emissions into the occupational, atmospheric, aqueous, or terrestrial environments. Emissions into the atmospheric environment comprise the following regulated, Pfizer stack-gas emissions: SO_2, NO_x and particulates. Emissions into the aqueous environment are negligible owing to the long residence time of production waste streams in the Pfizer Wastewater Treatment Plant. (See Section 2. Controls, c. Aqueous for a list of substances entering the treatment facility. See Appendix 3 for 5- and 20-day BOD data on polydextrose.) Emissions into the terrestrial environment may comprise small quantities of off-specification polydextrose from production start-up.

2. Controls - The following controls are used in the production of polydextrose to ensure compliance with general emissions requirements for workplace and environmental exposures.

a. Occupational. Workplace emissions, specifically of particulates, are controlled via appropriate equipment designs, materials and product transfer procedures, and worker protective equipment. Owing to the characteristics of the polydextrose process, process controls for specific regulated occupational emissions are not applicable. Monitoring of the work area is carried out to ascertain compliance with OSHA air contaminants regulations for nuisance dust. The Material Safety Data Sheet (MSDS) for polydextrose is included as Appendix 4.

b. Atmospheric. Particulate air emissions from the manufacturing process are controlled through the use of closed loop conveyor systems and vent filters on all single pass and closed loop systems. The filters are integral elements in the design of the conveyor systems, permitting both dust control and protection of the blower unit. Total particulate release is less than 75 lb/day. Stack-gas emissions from the Pfizer owned/operated power plant are controlled by baghouse filters, use of low-sulfur coal, and proper operation of the boilers.

c. Aqueous. Liquid discharges from the polydextrose manufacturing operation, comprising condensates, ion exchange system effluent, along with neutralized soluble solids of ion exchange acid and base regenerants of sulfuric acid and sodium hydroxide, and wash waters contain the following substances:

	CAS Reg. No.
glucose	50-99-7
sorbitol	50-70-4
citric acid	77-92-9
polydextrose	68424-04-4
1,6 anhydro-D-glucose (levoglucosan)	498-07-7
5-hydroxymethylfurfural	67-47-0
sodium hydroxide	1310-73-2
sulfuric acid	7664-93-9

These liquid discharges flow by gravity or are pumped to and then treated at the Pfizer owned and operated Wastewater Treatment Plant. This is an activated sludge, extended aeration, complete mix treatment process. This treatment, with a residence time of approximately 60 days, accomplishes a 99+ percent removal of BOD_5, and attains or exceeds the level of treatment necessary to meet the permit discharge limits for BOD, TSS, ammonia, oil & grease, phosphorous, COD, and pH.

d. Terrestrial. Solid wastes, comprised of paper, aluminum foil, plastic and fiber drums, plastic films and off-specification materials, are collected in dumpsters and disposed of at the local State-permitted sanitary landfill. An active waste minimization procedure continuously probes the materials and works to promote recycling or utilization of packaging components which are environmentally friendly.

3. Citation of Compliance

a. Occupational. Monitoring of the work area is carried out to ascertain compliance with the nuisance dust Permissible Exposure Limit (PEL: 10 mg per m^3), as specified in OSHA Air Contaminants 29 CFR 1910.1000.

b. Atmospheric. Air emissions are controlled in compliance with the following Indiana Administrative Codes (IAC):

326 IAC 2	Permit Review Regulations
326 IAC 5	Visible Emissions Regulations
326 IAC 6	Particulate Regulations
326 IAC 7	SO_2 Regulations
326 IAC 14-10-1	Emission Standards for Asbestos, Demolition and Renovation Operations

c. Aqueous. Liquid emissions are controlled to meet permit discharge limits approved in the Pfizer plant site National Pollutant Discharge Elimination System (NPDES) Permit No. IN0003581 issued in accordance with 40 CFR Parts 124 and 125, and 327 IAC 5-2.

Storm water discharge is controlled and monitored to achieve compliance with 40 CFR 122 and 327 IAC 5-4.

d. Solid. Solid wastes and nonhazardous special wastes are disposed of at a sanitary landfill operated in accordance with the following Indiana Administrative Code:

329 IAC 2-14	Landfill Regulations

Pfizer Wastewater Treatment Plant (WWTP) sludge wastes are disposed of by land applications, on both Pfizer- and Cultor Food Science-owned properties, according to:

327 IAC 6	Land Application Regulations

No wastes are generated which would meet the definition for hazardous as provided by Federal RCRA regulations 40 CFR Part 261, and Indiana regulations 329 IAC 3.1-6.

The subject action will not affect compliance with current OSHA workplace standards or with the above-defined current Federal and State emission requirements governing the subject polydextrose manufacturing facility.

We hereby certify that all emissions, discharges, wastes, and occupation requirements are now and will continue to be in compliance with OSHA standards and the applicable Federal, State and local emission requirements upon addition of the proposed action.

B. Use/Disposal. Polydextrose is incorporated into food products to serve a useful function, primarily in the formulation of reduced or low-calorie foods as permitted under 21 CFR 172.841. In such foods polydextrose substitutes for the bulk (but not the sweetness) of sugar and sometimes of fat.

1. Food Processing. Polydextrose is processed in the food industry in the manufacture of food products. Very little waste is generated in the manufacture of food products.

a. Quantities / Concentrations Emitted. Assuming about 0.5% of wastage from spillage, equipment washings and disposal of off-specification food products, an insignificant amount of polydextrose will be emitted into the environment as solid or liquid wastes by food manufacturers for all projected uses of polydextrose including the subject action (refer to Appendix 2 for total poundage estimates). Concentrations in treatment plant effluents are estimated to be insignificant owing to the biodegradability of polydextrose.

b. Treatment Processes. Emitted processing wastes are treated as conventional food wastes by food manufacturers, including liquid waste treatment plants and solid waste disposal.

c. Release Compartments. Release compartments comprise the aqueous (effluents from industrial and municipal waste treatment plants) and terrestrial (landfill wastes) environmental compartments. Negligible quantities of polydextrose may be emitted into the air compartment as dust from food manufacturing processes owing to standard use of vent filters to limit particulate emissions.

2. Consumer Use. As an ingredient in foods, polydextrose is ingested by humans. Based on metabolic studies in humans, orally administered polydextrose is essentially not absorbed and is mainly excreted in the feces. Approximately 25% of polydextrose is metabolized through partial degradation by microbial attack in the lower intestine to CO_2 and volatile fatty acids, a portion of which is absorbed and utilized as energy. For the purposes of this section, excreted materials from human ingestion will be termed "polydextrose".

a. Quantities / Concentrations Emitted. Projected mean polydextrose intake for fruit and water ices was estimated in Section B of FAP 5A4478 to be 1.2 g/person/day, and for all approved and petitioned uses, 20.2 g/person/day. This estimate assumes usage in every food product within each food category and is not realistic. Market penetration indicates that not more than 10% of theoretical can be expected. In addition, it is estimated that not more than 10% of the user population will be ingesting a polydextrose-containing food in any given day. Therefore, a more reasonable estimate of average intake would be 0.012 g/person/dy for fruit and water ices and 0.20 g/person/day for all approved and petitioned uses. In a population of 260 million in the U.S., excretion of polydextrose, assumed to be 75% of the amount ingested, would be 1.9 and 31.3 million pounds per year, respectively. (This theoretical level also is exaggerated based on production poundage projections - see Appendix 2). Assuming that 70% of U.S. sewage is treated in publicly owned treatment works (POTW's) which are estimated to handle $9x10^{13}$ pounds of water per year, the concentration of polydextrose in water entering POTW's would average 0.014 ppm (1.3 million pounds) for fruit and water ices and 0.24 ppm (21.9 million pounds) for all approved and petitioned uses. The remaining 30% of U.S. sewage would be widely dispersed through soil via cesspools and septic tanks, at comparable concentration. (Calculations may be found in Appendix 5).

b. Treatment Processes. As noted above, approximately 70% of the excreted polydextrose will enter POTW's; the remaining 30% will be handled in cesspools and septic tanks. Assuming an average residence time of about five days in these treatment systems and a biodegradation rate comparable to that in the BOD test (Appendix 3), resulting in an estimated 25% additional biodegradation, the quantity and concentration of polydextrose entering the environment from cesspools and septic tanks would be 0.43 and 7.0 million pounds and 0.011 and 0.18 ppm from fruit and water ices and from all approved and petitioned uses, respectively. The total amount of polydextrose entering the environment from POTW's and cesspools/septic tanks combined would be 1.7 and 29 million pounds and 0.023 and 0.22 ppm from fruit and water ices and from all approved and pending uses, respectively. (Calculations may be found in Appendix 5).

c. Release Compartments. The primary release environment for polydextrose emitted from sewage treatment systems will be the aqueous environment comprising rivers or other waterways adjacent to POTW's and the subterranean aqueous environment adjacent to cesspools and septic tanks. In addition some smaller quantities may be released as a component of sewage sludge, which is usually disposed of by landfill or incineration after drying.

d. Other. Unused consumer products containing polydextrose are disposed of either through sewage as described above or through solid waste, i.e. garbage disposed of as landfill or by incineration. The quantity of polydextrose in such wastes is probably less than 10% of that actually ingested through use in foods. The substance is not used in food packaging at this time.

7. FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT:

A. Air. Negligible quantities of polydextrose may be emitted into the air compartment as dust from food processing facilities. Consequently, assessment of polydextrose fate in air is judged not applicable.

B. Water Ecosystems. As noted in Section 6 above, the major environmental compartment for polydextrose released into the environment is water adjacent to municipal waste water treatment facilities or private septic systems. The maximum initial concentration of polydextrose (and its human and microbiological partial metabolites) in the water ecosystem is estimated at about 0.23 ppm (see Section 6, B, 2(b) above). Owing to the physical and chemical characteristics of polydextrose and its partial metabolites, emissions are expected to remain in the aqueous environment and not absorb to soil.

Prediction of the ultimate fate of polydextrose and its partial metabolites in the water ecosystem can be derived from (a) BOD data and (b) literature information on the biodegradation of related substances. As noted in Section 5 above, polydextrose is comprised essentially of glucopyranose moieties condensed primarily as α- and β-1, 6-, 1,4- and 1,3- linkages (with insignificant amounts of the 1,2- and 1,1-linkages). These linkages are present in a variety of naturally-occurring glucopolysaccharides; moreover, enzymes are known that can cleave the glycosidic linkages known to occur in polydextrose [N. K. Matheson and B. V. McCleary in "The Polysaccharides" (G. O. Aspinall ed.), vol. 3, pp. 1-105. Academic Press, New York, 1985. (See Appendix 6) for a summary listing of pertinent enzymes.] Based on this literature, polydextrose in the aqueous environment would be expected to be degraded by microorganisms in the environment to the component glucose and di-, tri-, etc., glucoside fragments which would then be metabolized completely.

Support for this prediction comes from the BOD data reported in Appendix 3. Using standard 5- and 20-day BOD tests with representative sewage organisms, polydextrose biodegradability was compared with two other polysaccharides: cotton, which is almost 100% cellulose, and ground newsprint, which contains about 65% cellulose as well as lignin and printing inks. A sample of polydextrose from which the low molecular weight material had been removed by gel filtration was also run (as polydextrose$_H$).

As can be seen from the data, a portion of the polydextrose is rapidly oxidized, more rapidly than the cotton or newsprint. After the initial rapid oxidation phase, the polydextrose oxidation continues at a slower rate, but at a rate as fast as or faster than that for cotton or newsprint. Since the oxidation rate of polydextrose is faster than the rate of these other materials, which are known not to accumulate in the environment, polydextrose would be expected to be completely degraded in the aqueous environment.

C. Terrestrial. Soil microorganisms may be expected to metabolize polydextrose in a manner similar to that in the aqueous environment, as the BOD tests cited above indicate the biodegradability of the substance. Consequently, the small quantities of polydextrose-containing wastes that may be landfilled (e.g., garbage or sewage sludge), would be expected to be completely biodegraded.

The Food and Drug Administration, in reviewing FAP 9A3441, concluded that polydextrose was exempt from preparing an Environmental Impact Analysis Report (refer to Appendix 7).

8. ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES:

The only environmental compartment subjected to significant amounts of released polydextrose and metabolites is the water ecosystem. As noted in Section 7B above, the maximum initial concentration of polydextrose in the aqueous environment is about 0.23 ppm. Ultimately, all polydextrose would be expected to be fully degraded and utilized by environmental microorganisms. The only concern, therefore, would be potential acute toxicity to aquatic organisms.

A search of the literature did not turn up evidence for toxicity of polysaccharides, as a class, to aquatic organisms (plants, vertebrates, or invertebrates). This is not unexpected inasmuch as polysaccharides are ubiquitous in the environment, serving as structural substances and/or energy storage and/or food for a wide variety of living organisms.

A single toxicity test with polydextrose was carried out in bluegills. The no-effect level of polydextrose toward Lepomis macrochirus (Bluegill sunfish) was greater than 20,000 mg/1, the highest concentration tested (see Appendix 8 and FAP 9A3441, Section H). No effects on survival or behavior were seen during or after the test. Thus, polydextrose is nontoxic to Bluegill sunfish at a level that is about 85,000 times the level expected to be found in water ecosystems (0.23 ppm), and is unlikely to have any adverse effects on other aquatic organisms.

Because microorganisms have been demonstrated in BOD tests to thrive on polydextrose, adverse effects upon microorganisms in the environment are extremely unlikely. Also, as an inert polysaccharide, polydextrose in unlikely to have any effect on plants. Eleven years of full scale experience in the production of polydextrose have not revealed any environmental concerns.

The safety of polydextrose to humans and other mammals is documented in FAP 9A3441, Section E.

9. USE OF RESOURCES AND ENERGY:

Production of polydextrose is carried out in four buildings covering less than 2.0 acres of land within the plant site; consequently, there will be no alteration of existing land use from the subject action. No significant amounts of non-renewable resources or of resources that are in short supply are or will be used in the production process or to transport, use, or disposal of the product, or in the waste disposal associated with production and use of the product. The only renewable resources that are or will be used in quantity are the major components of the product, namely, glucose and sorbitol. No substantive increase in use of resources and energy is projected for production, use, etc, of polydextrose as a result of the subject action.

Approximately 600,000 BTU's of fuel (coal and oil) and electricity are required to produce 100 pounds of polydextrose, including disposal of the very small amounts of wastes from the process. Energy required for transport of the product to users, for use in food manufacture, and for disposal, should this be needed, is judged negligible.

There are no expected effects upon endangered or threatened species nor upon property listed in or eligible for listing in the National Register of Historic Places.

10. MITIGATION MEASURES:

Measures to control accidental release or occupational exposure during manufacture and use of polydextrose are described in detail in the format Item 6, above. Inasmuch as the subject manufacturing process has been on stream for a number of years, no risk is foreseen in increasing production to meet the subject action. Nonetheless, a number of mitigative measures can be projected in the event that controls fail. These include:

a. Workplace. Spill response procedures and suitable containment features in the subject manufacturing equipment and building configuration;

b. Atmospheric. Shut-down and corrective maintenance and repairs if controls on dust emissions fail; shut-down and repair procedures if the Pfizer owned/operated coal-fired boiler emissions exceed permitted levels;

c. Aqueous. Use of holding ponds in the unlikely event that the Pfizer WWTP emissions exceed permitted discharge limits from overload and/or malfunction of the treatment plant;

d. Terrestrial. Use of a holding pond in the event that land application of Pfizer WWTP sludge is temporarily curtailed.

Contamination of the product with foreseen or unforeseen impurities that could have an adverse effect on product use are precluded by (1) careful control over the entire manufacturing procedure, (2) application of stringent quality control procedures during manufacture, and (3) existence of stringent release specifications that are specific to the subject polydextrose process and that have already been proven out in manufacture of polydextrose for other approved food uses. (See FAP 9A3441, Section A, for details relating to product quality assurance.)

11. ALTERNATIVES TO THE PROPOSED ACTION:

The production process for polydextrose employs common food-grade materials in an efficient, trouble-free process that has been on stream for several years. The manufacture and use of polydextrose results in emission of substances that will not accumulate in the environment and are intrinsically safe to the environment. Consequently, no potential adverse environmental impacts have been identified in the production and use of polydextrose for presently-approved food uses, and no further environmental impact is foreseen from the subject action. Therefore, no alternatives are presented in this document.

12. LIST OF PREPARERS:

Mr. Terry E. Maddux, Engineer with BS degree in Chemical Engineering, 19 years of diverse production experience and 9 years as Polydextrose Manager for Terre Haute facility.

Mr. Mark Middleton, Maintenance and Environmental Manager with BS degree in Mechanical Engineering, 15 years industrial maintenance/engineering experience.

Mr. Edward G. Merritt, Chemist with BA degree in Chemistry-Zoology and 16 years experience in technical service, 4 years in marketing and headquarters operations, 16 years as Associate Director Compliance and Regulatory Affairs in Chemical Products R&D, Pfizer Central Research, and 5 years consultant to Pfizer Central Research/Cultor Food Science.

13. CERTIFICATION

The undersigned official certifies that the information presented is true, accurate, and complete to the best of Cultor Food Science's knowledge.

Name: Douglas W. Cartwright   Title: Plant Manager, Terre Haute

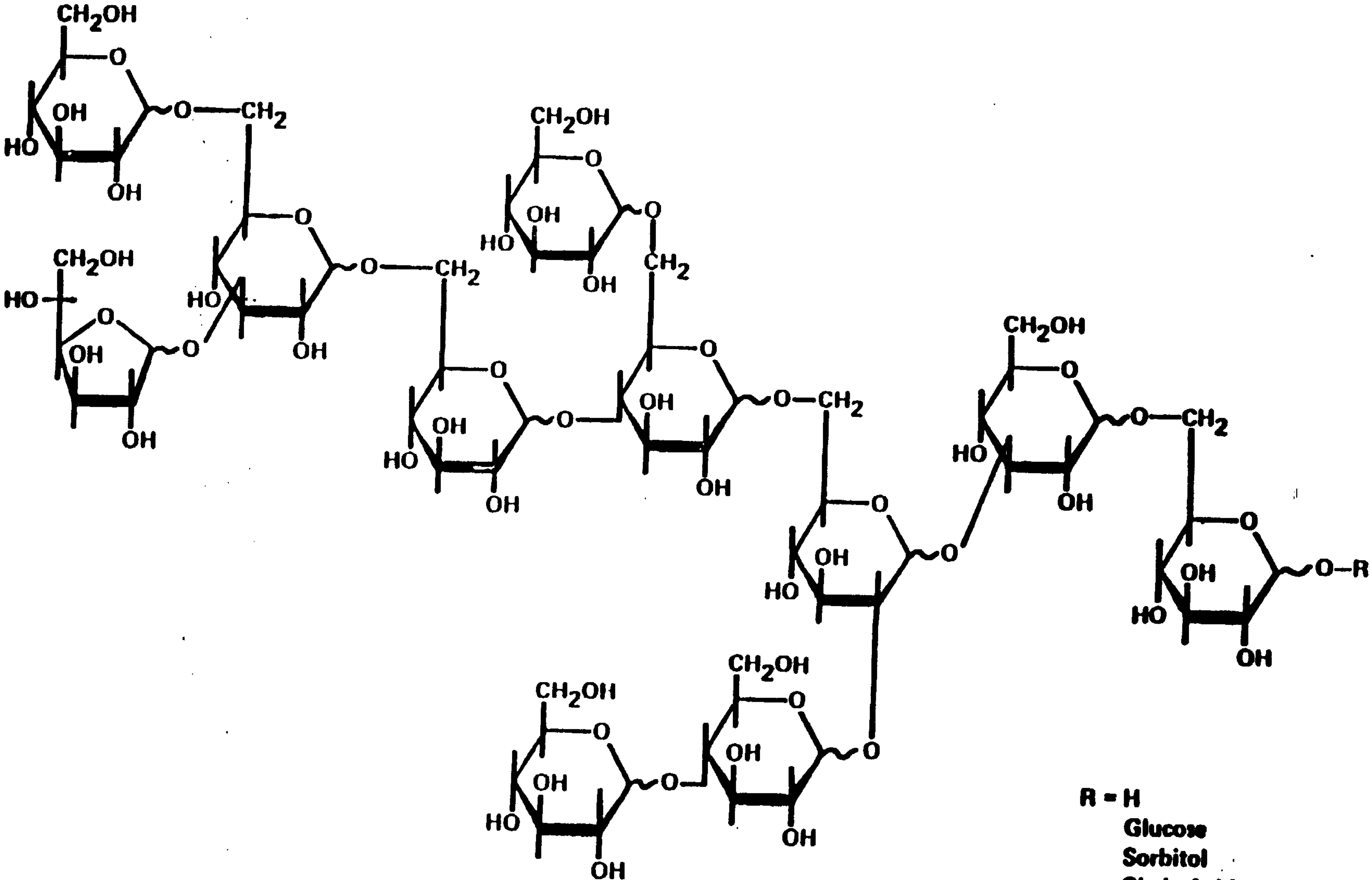
Douglas W. Cartwright   June 24, 1996

Signature   Date

Appendices:

1. Structural Formula (illustration)
2. Polydextrose Poundage Estimates (CONFIDENTIAL)
3. BOD Data (5 & 20 day)/BOD/COD Test
4. Material Safety Date Sheet (MSDS)
5. Emission Calculations
6. Literature Documentation of Enzymes
7. FDA letter of February 12, 1979
8. *Lepomis macrochirus* (Bluegill Sunfish) Test

Appendix 1



R = H
Glucose
Sorbitol
Citric Acid
Polydextrose

Illustration of Chemical Bonds Present in Polydextrose

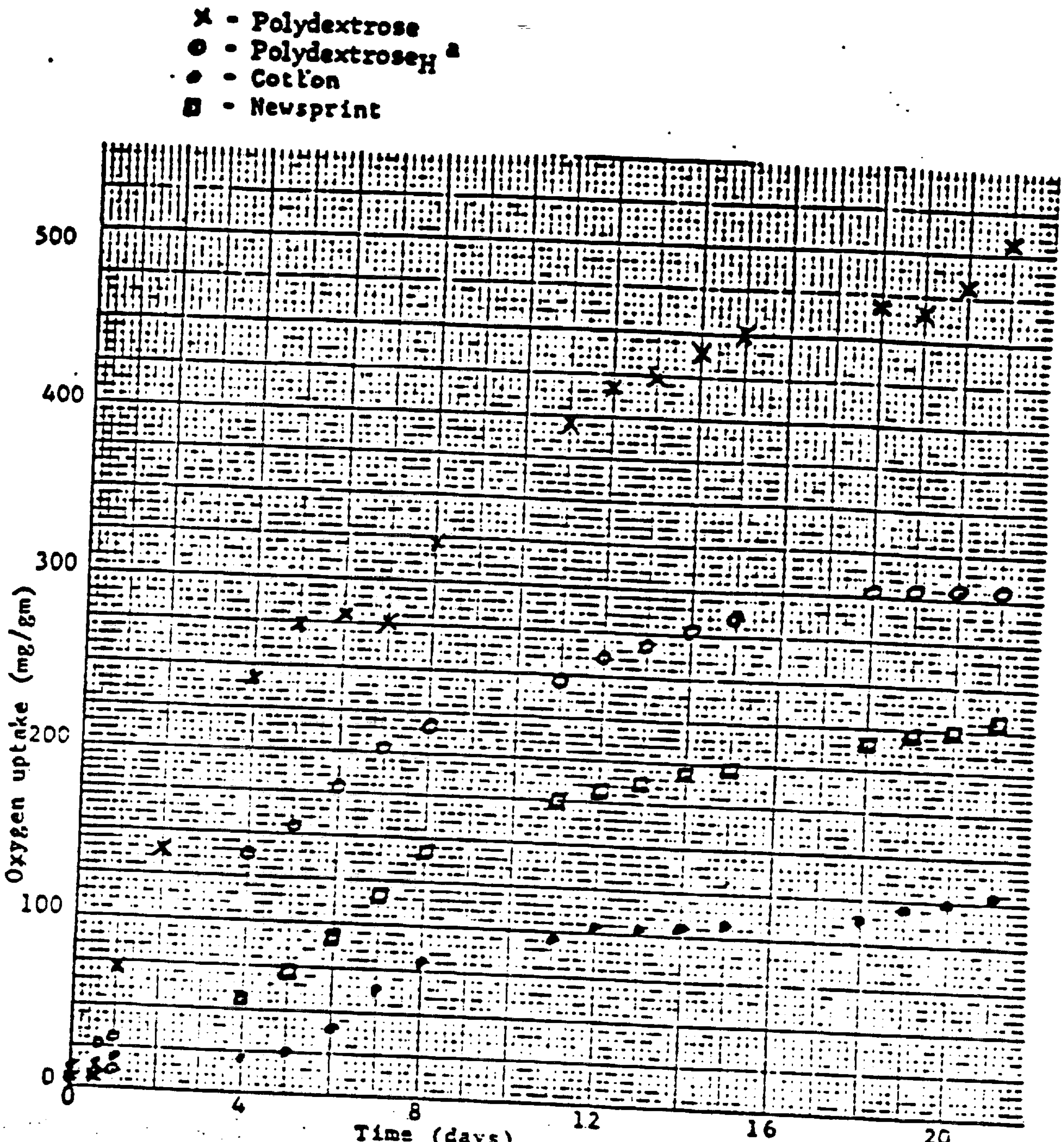
CONFIDENTIAL

Appendix 2

Redacted version

CONFIDENTIAL

Biological Oxidation of Polydextrose, Cotton, and Newsprint.



Conditions: Hach Manometric BOD Apparatus. Raw sewage seed, synthetic dilution water (Standard Methods), 20°. All data corrected for oxygen uptake due to seed.

[a] Polydextrose from which low molecular weight material was removed by gel filtration.

Biological Oxidation of Polydextrose, Cotton, and Newsprint.

material	Oxygen Uptake (mg/gm material) 5-day	20-day	theoretical[c]	Percent of Theoretical Oxidation 5-day	20-day
polydextrose	280	485	1,189	23.5%	40.8%
$polydextrose_H$[a]	180	305	1,189	15.1%	25.6%
cotton	40	125	1,185	3.4%	10.5%
newsprint[b]	72	225	770	9.4%	29.2%

[a] Polydextrose from which low molecular weight materials was removed by gel filtration.

[b] Ground to pass through a .065" mesh screen.

[c] Chemical Oxygen Demand (COD) for Polydextrose and $Polydextrose_H$; Calculated for 100% cellulose in cotton, 65% cellulose in newsprint. The following method was employed:

1. For a typical polymer.-

   a. assume full oxidation:
   $$(C_xH_yO_z)_m + n\ H_2O \rightarrow x\ CO_2 + (y/2)H_2O$$

   b. compute n:
   $$n = x + (y/2) - z$$

   c. compute mg O_2/g polymer using m = 1:
   $$\frac{n(32)}{\text{M. Wt. of } (C_xH_yO_z)} \times 1000 = COD$$

2. For polydextrose and $polydextrose_H$.-

   a. assume 89% glucose, 10% sorbitol, 1% citric acid

   b. compute COD's for each, using M. Wts. for the anhydro polymeric form of each:

	anhydro form	COD
glucose	$(C_6H_{10}O_5)$	1,185
sorbitol	$(C_6H_{12}O_5)$	1,268
citric acid	$(C_6H_8O_7)$	750

   c. compute COD:
   $$0.89(1,185) + 0.10(1,268) + 0.01(750) = 1,189$$

CULTOR

CULTOR FOOD SCIENCE

MATERIAL SAFETY DATA SHEET

Polydextrose

Date Issued: 3/87
This Revision: 6/18/96

MSDS number P005

MANUFACTURER: Cultor Food Science, Inc.
205 East 42nd Street
New York, NY 10017

EMERGENCY TELEPHONE:
212 573-2222

SECTION I: PRODUCT IDENTIFICATION

Tradename:	Litesse
Chemical name:	Polydextrose
Chemical Family:	Polysaccharide
Formula:	$(C_6 H_{12}O_6)_x$
CAS Number:	68424-04-4

SECTION II: HAZARDOUS INGREDIENTS

None

SECTION III: PHYSICAL DATA

Molecular Weight:	2000-3000 wt. avg.
Appearance:	White to light tan powder
Melting point:	~150-160°C
Boiling point:	Decomposes
Solubility:	Extremely soluble in water, 70-80%
pH of 10% aqueous solution:	2.5-3.5
Odor:	Little to none

SECTION IV: FIRE AND EXPLOSION HAZARD DATA

Ignition point (dust):	975°C
Flammable Limits:	Min. Lel 13 g/ft^3 ; Opt. Uel 40 g/ft^3
Extinguishing Media:	Water
Special Fire Fighting Procedures:	None required
Unusual Fire and Explosion Hazards:	Bureau of Mines relative explosion rating for dust is "moderate" at optimum air concentrations; material does not require classification under DOT regulations.

SECTION V: HEALTH HAZARD DATA

FHSA Acute Toxicity:	Mouse oral LD50 > 30 g/kg.
Chronic:	Polydextrose is an approved food additive under 21 CFR 172.841
Mutagenicity/Carcinogenicity:	Not listed

Effects of Overexposure (Routes of entry -- skin and eye contact, dust inhalation, ingestion):

Eye:	May cause mild irritation.
Skin:	No adverse effects reported.
Inhalation:	No adverse effects reported.
Ingestion:	No TLV established. Sensitive individuals may experience a laxative effect from excessive consumption.

Emergency First Aid Procedures:

Eye:	Flush eyes with plenty of water. Seek medical attention if irritation persists.
Skin:	Not applicable.
Inhalation:	Remove to fresh air. Accidental inhalation of small amount of dust is not expected to cause adverse effects.
Ingestion:	None required.

SECTION VI: REACTIVITY DATA

Stability:	Stable
Incompatibility (materials to avoid):	Strong oxidizing agents, strong acids (e.g. nitric, sulfuric)
Conditions to avoid:	None known
Hazardous Decomposition Products:	None known
Hazardous Polymerization:	Will not occur

SECTION VII: SPILL OR LEAK PROCEDURES

Small Spill:	Remove by vacuum, scoop or shovel, then flush area with water to remove final traces.
Large Spill:	
Waste Disposal:	Dispose in compliance with applicable federal, state or local regulations. Landfill or incineration of dampened powder should be considered.

SECTION VIII: SPECIAL PROTECTION INFORMATION

Respiratory Protection:	None normally required
Ventilation:	Normal room ventilation for dust removal
Protective Gloves:	None normally required
Eye Protection:	Safety glasses
Other Protective Equipment:	None required

SECTION IX: SPECIAL PRECAUTIONS

Storage and handling:	Store away from strong oxidizing agents or strong acids (e.g. nitric, sulfuric). No other precautions normally required.

This MSDS is based on a review of Cultor files, literature references, toxicology handbooks, and published MSDS's on identical or related materials.

This information is furnished without warranty of any kind. It is intended as a guideline and is not a substitute for consulting the appropriate regulations and source materials for appropriate protection for your employees who may come into contact with the product. The determination of whether and under what conditions the product should be used by your employees is yours to make.

Appendix 5

Redacted version

Literature Documentation of Enzymes Capable of Cleaving Glucosidic Linkages Such as Those Found in Polydextrose.-

Polydextrose has been determined to be comprised predominately of glucose moieties in the pyranose form, with about 9% in the furanose form. Linkages have been determined to be 1,6-(~60%), 1,4-(~20%), 1,3-(~20%), with negligible amounts of 1,2- and 1,1-linkages. Configurations at the 1-position are estimated to be α:β=1:1. Determination of the gross structure of polydextrose, as illustrated in the idealized diagram in Appendix 1 showing the major structural features (linkages and branching), was carried out by analysis of products of periodate oxidation, Smith degradation and partial hydrolysis to disaccharides (refer to FAP 9A3441, Volume 11, pp. 8-22).

The various random glucosidic linkages found in polydextrose have counterparts in nature. Moreover enzymes are known that can cleave these linkages. A delineation of these enzymes and their natural substrates can be found in the review by N. K. Matheson and B. V.. McCleary in "The Polysaccharides" (G. O. Aspinall, ed.), vol. 3, pp. 1-105, Academic Press, New York, 1985, summarized below, pertinent pages appended.

The subject enzymes are termed "endo glucanases". They have hydrolytic activity vs interior glucosidic linkages, generally requiring a region of un- or lightly-branched glucan chain. As a result of their actions, the end-products of their enzymatic hydrolytic activities are low-molecular weight oligosaccharides. These enzymes have activity vs (a) mixed glucans [eg, (1-3)(1-4)-β-D-glucans such as lichenan and cereal gums which can be degraded by cellulase, 1,3(4)-β-glucanase and lichenase], and (b) branched glucans [eg, (1-6) in (1-4)(1-6)-α-glucans (degraded by isoamylase) and (1-2) in (1-2)(1-6)-linked dextrans (degraded by dextranases)]. [In addition there are exo enzymes capable of cleaving end-moieties from, for example, exo-1,3-β-, 1,3-α, 1,6-α-, and 1,3-α-glucosidic chains.]

See table on next page for a summary of glucosidic linkages, natural substrates, and enzymes that are functional in cleaving the glucosidic linkages.

LINKAGES	SUBSTRATES	ENZYMES
α-1,6-	microbial carbohydrates; eg, pullulan, amylopectins, dextran [mixed (1-2)(1-6)]	fungal and bacterial endo-1,6-α-glucanases; eg, pullulanases
β-1,6-	yeast and bacterial cell walls and polymers; eg, pustulan, laminaran, succinoglycan	fungal and bacterial endo-1,6-β-glucanases
β-1,4-	cellulose; also lichenan and cereal glucans that are mixed (1-3)(1-4)	bacterial cellulases (cellobiases, cellobiohydrolases, endo-1,4-β-glucanases)
α-1,4-	starch; amylose, amylopectin, maltose, pullulan, elsinan glycogen, nigeran [mixed (1-3)(1-4)]	ubiquitous α-amylases (mammals and microorganisms)
β-1.3-	yeast cell walls, laminaran, lichenan, cereal glucans, curdlan and pachyman, scleroglucan	endo-β-1,3-glucanases of microorganism origin, pullulanase
α-1,3-	fungal cell wall polysaccharides, dextrans[mixed (1-2)(1-6)], nigeran [mixed (1-3)(1-4)]	bacterial endo-1,3-α-glucanase, nigerase
α-1,2-	dextrans	corn α-D-glucosidase, dextran -1,2-α-debranching enzyme
β-1,2-	laminaran [mixed (1-2)(1-6)], sophorose	endo-1,2-β-glucanases